PFAS Background and Considerations for Pesticide Inert Ingredients

Presentation to OPP Office Director

June 21, 2022

RD--Beth/Debra

Outline:

- Meeting Purpose
- PFAS Background
- Inert Ingredients
  - Communications Discussion
- OPP Strategy for Pesticides that fall under the PFAS Definition
  - Future briefing on considerations for active ingredients defined as PFAS

RD--Beth/Debra

Meeting Purpose:

- Provide an overview of PFAS Agency strategy, definitions, and potential regulatory considerations associated with pesticide registrations

- Inert ingredients
  - List of inerts compiled and submitted by PEER
  - Status of listed/registered inert ingredients identified as PFAS

- Future steps
  - Discuss any needed Agency-level communication strategy for inert ingredients, considering the current PFAS Strategic Roadmap (October 18, 2021)
  - OPP Strategy for Pesticides that fall under the PFAS Definition
    - Discuss future briefing on considerations for active ingredients defined as PFAS

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PFAS Background

INTERNAL, DRAFT DELIBERATIVE

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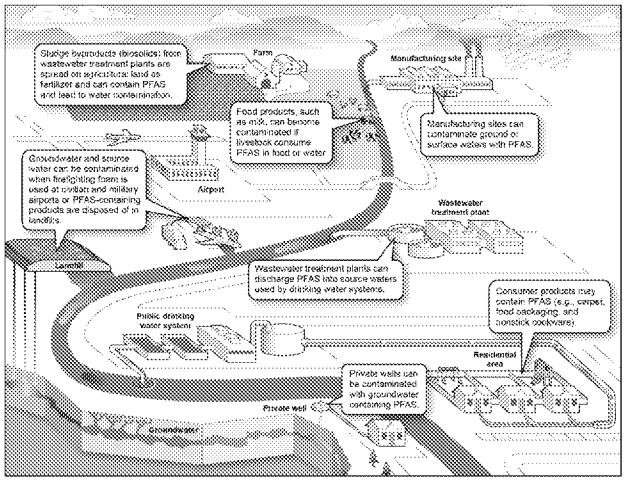
Broad PFAS Concerns:

- PFAS are a large class of chemicals with varying degrees of human toxicity linked with cancer, reproductive, developmental, liver, kidney, thyroid, and immunological effects (i.e., chronic effects).
- PFAS compounds are generally persistent and accumulate in the environment.
- The nature of effects across different taxa is variable; for aquatic taxa effects are observed at low concentrations.
- EPA developed a roadmap to research, restrict, and remediate PFAS contamination.

[1] https://www.epa.gov/system/files/documents/2021-10/pfas-roadmap_final-508.pdf

Jeff

Roadmap - PFAS Lifecycle and Principles:



PFAS Strategic Roadmap: EPA's Commitments to Action 2021–2024

EPA's approach is centered around the following principles:

- Consider the Lifecycle of PFAS.
- Get Upstream of the Problem.
- Hold Polluters Accountable.
- Ensure Science-Based Decision-Making.
- Prioritize Protection of Disadvantaged Communities.

Source: GAO | GAO-21-37

Jeff

Goals in the Strategic Roadmap

RESEARCH

Invest in research, development, and innovation to increase understanding of

- PFAS exposures and toxicities;
- Human health and ecological effects; and
- Effective interventions that incorporate the best-available science.

RESTRICT

Pursue a comprehensive approach to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment.

REMEDIATE

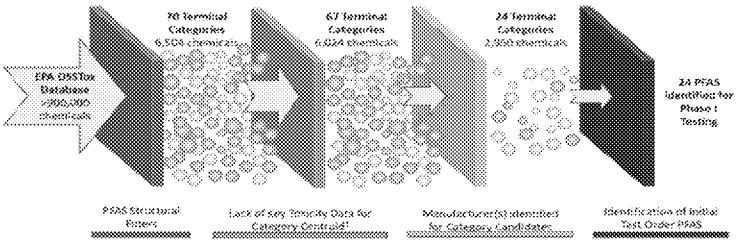
Broaden and accelerate the cleanup of PFAS contamination to protect human health and ecological systems.

PFAS Strategic Roadmap: EPA's Commitments to Action 2021–2024

Jeff

Analysis Supporting Testing Efforts:

- National Testing Strategy
  - Identified 70 distinct categories
  - Applied a series of structural filters to create categories
  - Described in https://www.frontiersin.org/articles/10.3389/fenvs.2022.850919/full



Ring structures of broflanilide and PQZ excluded these chemicals from the testing strategy.

Jeff

PFAS Definition Issue:

- OCSPP is using OPPT PFAS definition
  - OPPT PFAS definition: R-CF_2R-CF(R')(R") where R, R', R" do not equal H and the C-C bond is saturated
  - OECD PFAS definition: fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it)
- OW is considering options for expanding definition, also OPPT is considering expanded options under 8(a)7 rule.
- Use of OECD PFAS definition would increase the number of designated active ingredients from 2 to ~100.

RD—Kerry

Resources for Agency Efforts on PFAS:

- General Info https://www.epa.gov/pfas
- PFAS Council https://www.epa.gov/sites/default/files/2021-04/documents/per-and_polyfluoroalkyl_substances.memo_.signed.pdf
- PFAS Roadmap https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024#council
- PFAS National Testing Strategy https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/national-pfas-testing-strategy

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Inert Ingredients

RD--Kerry and/or Evisabel

PFAS and Inert Ingredients-Background:

- In Feb of 2021 PEER[1] provided OPP with a list of 24 inert ingredients found in OPP's InertFinder[2] database believed to be PFAS.
- The PEER list was based on an ORD database with literature references of PFAS, and not a specific PFAS definition.
- Also, listing on InertFinder only means that a substance is approved as an inert ingredient, but it may not be currently used in registered pesticide products.

[1] PEER = Public Employees for Environmental Responsibility

[2] https://ordspub.epa.gov/ords/pesticides/f?p=INERTFINDER:1:0::NO:1::

RD--Kerry and/or Evisabel

PFAS and Inert Ingredients-Background:

- Are any of the chemicals listed on the PEER document PFAS chemicals based on current definitions (per OPPT and OECD) and if so, are they currently used in pesticide products?

- In collaboration with ORD's Center for Computational Toxicology and Exposure, a search was conducted to determine whether any inert ingredients on InertFinder met either the OPPT or OECD definitions.

RD- Evisabel

PFAS and Inert Ingredients – Analysis:

- Eight chemicals from InertFinder (also identified on the PEER list) met either the OPPT definition or met the OECD definition of a PFAS chemical and had at least one product associated with it (per OPPIN):

CAS Reg No	Ingredient Name	Food/ Non-food	Meets OPPT or OECD definition
131324-06-6	Poly(difluoromethylene), alpha-chloro-omega-(1-chloro-1-fluoroethyl)-	NF	Yes OPPT Yes OECD
163440-89-9	Poly(difluoromethylene), alpha-(2,2-dichloro-2-fluoroethyl)-, omega-hydro-	NF	Yes OPPT Yes OECD
24937-79-9	Ethane, 1,1-difluoro-, homopolymer	NF	No OPPT Yes OECD
25067-11-2	Hexafluoropropene, polymer with tetrafluoroethylene	NF	Maybe OPPT Yes OECD
65530-66-7	Poly(difluoromethylene), .alpha.-fluoro-.omega.-[2-[(2-methyl-1-oxo-2-propenyl)oxy]ethyl]-	NF	Yes OPPT Yes OECD
65530-85-0	alpha-(Cyclohexylmethyl)-omega-hydropoly(difluoromethylene)	NF	Yes OPPT Yes OECD
65545-80-4	Poly(oxy-1,2-ethanediyl), alpha-hydro-omega-hydroxy-, ether with alpha-fluoro-omega-(2-hydroxyethyl)poly(difluoromethylene) (1:1)	NF	Yes OPPT Yes OECD
79070-11-4	Poly(difluoromethylene), .alpha.-chloro-.omega.-(2,2-dichloro-1,1,2-trifluoroethyl)-	NF	Yes OPPT Yes OECD

- An additional 10 chemicals met the OECD definition only (2 food, 8 non-food) but either had no product associated with them or were for food use

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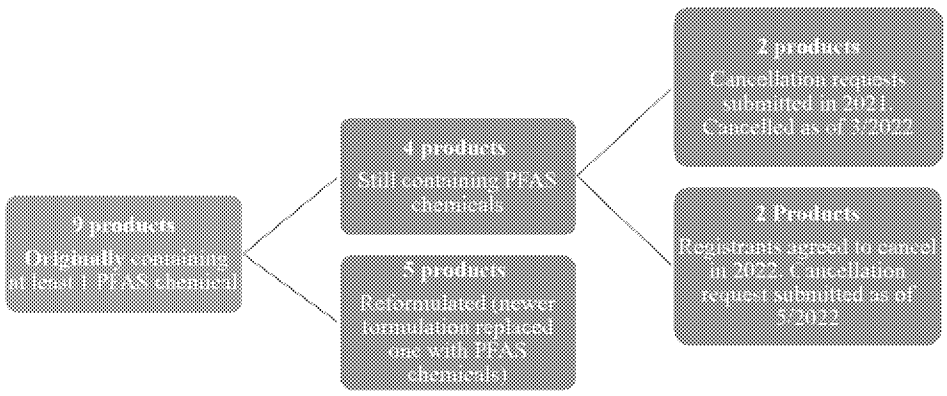
PFAS and Inert Ingredients – Results:



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PFAS and Inert Ingredients – Next Steps:

Ex. 5 Deliberative Process (DP)

1. Per OPPT PFAS definition

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Active Ingredients

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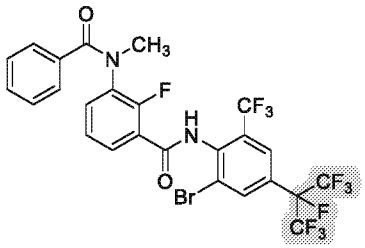
RD--Debra/Beth

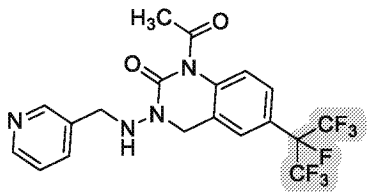
PFAS Pesticide Active Ingredients:

- Two pesticides classified as PFAS chemicals under the OPPT definition.

Broflanilide



PQZ



RD--Debra

Considerations for Active Ingredients Defined as PFAS:

- Collaborated with ORD to evaluate issue
  - As noted, broflanilide and PQZ were excluded from national testing strategy
    - Structures are curated in the ORD Dashboard
    - No data beyond pesticide database
  - Asked ORD to also search for degradates from the ROCKS memos
    - Structures were not in ORD dashboard but can be added
    - No data identified
- Projected overlay with testing strategy if structural filter for ring structure removed
  - Broflanilide and PQZ would likely end up in "Others, gte8,2,3" & "Others, gte8,2,2"
  - This category is not one of the first 24 test order categories
  - Similar outcome for degradates

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OPP Strategy for Pesticides that fall under the PFAS Definition:

Ex. 5 Deliberative Process (DP)

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Background Information for PFAS Active Ingredients

INTERNAL, DRAFT DELIBERATIVE

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Broflanilide Registration Status:

- First registered in 2021.
- Agricultural application methods include in-furrow (corn and subgroup 1C) and seed treatment (small grains)
- Also registered for control of insects inside and around industrial, commercial (including food handling establishments), and residential areas.

Broflanilide Pending Uses:

Ex. 5 Deliberative Process (DP)

INTERNAL, DRAFT DELIBERATIVE

RD—Beth
Applied using handheld sprayers, applicator tubes (gel formulations), aerosol cans, injection systems, and Centrobulb® equip

Broflanilide--Comments received on NOR

- Notice of Receipt (NOR) for the corn seed treatment use published 4/26/2022 and the comment period closed on 5/26/2022.
- 9 comments were received on the NOR
  - 4 general, non-substantive comments from private citizens requesting the Agency not approve any uses, including 1 saying to not approve because it meets the definition of PFAS
  - 1 Pollinator Stewardship Council and Earth Justice--the risks to pollinators, fish, aquatic invertebrates, birds, and other animals outweigh the benefit of controlling soil-dwelling pests
  - Center for Biodiversity (CBD)—Strategic Roadmap efforts for PFAS are undermined by approval and use of Broflanilide.
  - Letter from the CBD on behalf of 35 public health, environmental justice, and farmworker and farmer advocates urging the EPA to cancel the registration of the exiting uses and deny the application to expand its use on treated corn seed
    - Comment also mentions that Broflanilide is a PFAS chemical
  - Pollinator Stewardship Council—additional data is needed on impact to ground dwelling/nesting bees
  - USDA--highly beneficial development for integrated pest management (IPM) programs, given novel mode of action and potential for managing resistance among a wide variety of soil-borne pests, especially wireworms. Corn seed treatment as a new use would significantly benefit IPM efforts

PQZ Registration Status:

- First registered in 2013 for indoor ornamental uses
- Currently registered for use on multiple commodities.
- Approved application methods include aerial, ground (chemigation, air blast).

Pending use[1]:

Ex. 5 Deliberative Process (DP)

[1]Pending first residential uses are awaiting ESA completion.

RD--Debra

Human Hazard Summary

Broflanilide

- Absorption and excretion is rapid, no evidence of bioaccumulation.
- Target organs are the adrenal glands and ovaries.
- Broflanilide is classified as "likely to be carcinogenic to humans"

PQZ

- No evidence of bioaccumulation of PQZ at relevant doses
- Target organs are the testes, nasal passage, liver, thyroid, hematopoietic system and the kidneys.
  - Observed effects include decreased anogenital distance and decreased postnatal body weights
- PQZ is classified as "Not likely to be carcinogenic to humans"

Both pesticides have:

- Comprehensive and complete AI-specific datasets in support of proposed pesticidal uses (i.e., not considering PFAS as residue of concern). Any human health effects of parent and its observed metabolites would be expected to be captured in the studies.

HED teams

Environmental Fate Summary:

Broflanilide

- Broflanilide and known major (>10%) PFAS-containing metabolites are persistent in the environment
  - No fate for terminal PFAS degradate
- Parent and degradates likely to accumulate in aquatic and terrestrial environments

PQZ

- PQZ and known major (>10%) PFAS-containing metabolites are *not* persistent in the environment
  - Fate studies do not track to terminal PFAS degradate(s)
  - There may be currently unknown PFAS degradates that could persist in aquatic and terrestrial environments not captured in prior exposure assessments (drinking water and ecological)

EFED teams

Ecological Effects Summary:

Broflanilide

- No chronic data for PFAS degradates
- No studies for terminal PFAS degradates
- Chronic risks to birds and mammals on-field from consumption of treated seeds.
- Acute and chronic risks identified for terrestrial and aquatic invertebrates
  - Risk after a single application
  - Risk increases with subsequent applications
- Identified risks consistent with PFAS type chronic exposure and cumulative risk
  - Parent based assessment, parent is persistent

PQZ

- No chronic data for PFAS degradates
- No studies for terminal PFAS degradate
- Chronic risks identified for mammals
- Acute and chronic to terrestrial and aquatic invertebrates
  - Risk after a single application
  - Parent does not accumulate in the environment, so risk was not expected to increase over time from parent exposure or identified degradation products
- Risk assessment findings may not be protective of potential PFAS risks
  - Parent based assessment, parent is short lived

EFED teams
PQZ--we are concerned that the total accumulation of all PFAS degradates both known and unknown will be a risk issue.